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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,671	12/30/2003	Kanury Venkata Subba Rao	C261 1050.1	1554

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/747,671	RAO ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *10,11,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 1-14 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment and Response to Restriction Requirement filed June 28, 2006 has been received and entered into the application. Accordingly, claims 15-28 have been cancelled.

Election/Restriction

Insofar as Applicants have cancelled claims 15-28, the restriction requirement set forth in the previous Office action dated March 28, 2006 is rendered *moot* and therefore is *withdrawn*. Applicants' election of the species L-Aspartic acid, N-Sulfonic acid is acknowledged, said election having been made without traverse.

Claims 1-9 and 12 read on the elected species and are herein acted on the merits. Claims 10, 11, 13 and 14 are withdrawn from further consideration as being directed to non-elected subject matter. If the elected species if free of any art rejection, the Examiner will extend his search and consideration to include the next appearing species as set forth in present claim 12. Should the species of claims 9 and 12 be allowable, the Examiner will next extend his search and consideration of the species of claims 10 and 13, and then claims 11 and 14.

The references cited on the attached form PTO-892 and not relied on have been cited to show the general state of the art.

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. § 102, a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps*

Clinic & Research Foundation v. Genetech, Inc., 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue,* 766 F2d531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). To anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile,* 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable. See also MPEP §§ 2112, 2112.02 and 2145(II).

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

It should be noted that because the inventive entity of the following reference is <u>not the same</u> as the inventive entity of the present application, the reference can be properly characterized as being "by another" as provided for in 35 U.S.C. § 102(e).

Claims 1-3, 9 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Wani et al., (U.S. Patent No. 6,905,710).

Wani et al. teach a method for inhibiting osteoclast formation which comprises administering an effective amount of a hydrosylate extract from Indian green mussel, e.g., *Perna viridis*, to an animal or human in need thereof, (see, for example, the abstract). It is further disclosed that, as in present claims 2 and 3, the extract is effective for inhibiting the formation of multinuclear and mononuclear TRAP-positive osteoclasts, (see col. 2, line 66 – col. 3, line 18).

While Wani et al. do not disclose that the extract contains an effective amount of L-Aspartic, N-Sufonic acid, the Examiner has reason to believe that such is the case because the tenor of the disclosure in the present application at page 8, line 22 – page 9, line 19 is that the sulfonic acid derivatives of acidic amino acids are contained the extract as disclosed by Wani et al. Also, a comparison of "Reference example 11" in the present specification at pages 57-58 and "Example 1" at cols. 5-6 of the patent reveals similar activity in the tested conditions, both using Balb/c mice. Given the above, it is reasonable to conclude that the prior art product is a composition that comprises the presently claimed L-Aspartic, N-Sufonic acid. The Examiner is unable to offer actual proof of this matter. However, such does not diminish the propriety of the present rejection because, as set forth in the MPEP at § 2113, (last sentence), "As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972)."

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-1-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wani et al., (U.S. Patent No. 6,905,710), for the reasons set forth above, which reasons are here incorporated by reference.

The difference between the above and the claimed subject matter lies in that Wani et al. fail to disclose the effective amounts as in present claims 4-5 and the duration of treatment as in present claims 6-8.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because Wani et al. disclose that the concentration of the extract may exceed 100 μg/mL thus

allowing for dosage amounts which are not inconsistent with the presently claimed dosage amounts. "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. '[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.'" *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" (see MPEP 2144.05(II)). The determination of the optimum dosage and dosage regimen to employ, where the number of treatment days would vary as in the present claims, would have been a matter well within the purview of one of ordinary skill in the art and such determination would have been made in accordance with a variety of factors. These would have included the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered a part of a drug combination. Thus, the dosage regimen that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent the dosages that would have been determined by the skilled artisan.

Accordingly, for the above reasons, the claims are deemed properly rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,905,710. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented method is directed to a method for inhibiting osteoclast formation which comprises administering an effective amount of a hydrosylate extract from Indian green mussel, e.g., *Perna viridis*, to an animal or human in need thereof.

While Wani et al. do not disclose that the extract contains an effective amount of L-Aspartic, N-Sufonic acid, the Examiner has reason to believe that such is the case because the tenor of the disclosure in the present application at page 8, line 22 – page 9, line 19 is that the sulfonic acid derivatives of acidic amino acids are contained the extract as disclosed by Wani et al. Also, a comparison of "Reference example 11" in the present specification at pages 57-58 and "Example 1" at cols. 5-6 of the patent reveals similar activity in the tested conditions, both using Balb/c mice. Given the above, it is reasonable to conclude that the prior art product is a composition that comprises the presently claimed L-Aspartic, N-Sufonic acid. Reliance on the disclosure portion of the '710 patent appears proper as such is necessary to establish a reasonable

basis for concluding that the product of the patent claims contains the presently claimed amino acid derivative.

Also, while inhibiting the formation of multinuclear and mononuclear TRAP-positive osteoclasts is not highlighted in the patented claims, the claims nevertheless set forth "osteoclast" formation and such is deemed a sufficiently small genus so as to have placed either of the specific types presently claimed in the possession of the public.

Also, while the dosage amount or treatment duration, as presently claimed, is not set forth in the patented claims, it is set forth in patented claim 12 that the concentration of the extract may exceed 100 μg/mL thus allowing for dosage amounts which are not inconsistent with the presently claimed dosage amounts. "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. '[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.'" *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" (see MPEP 2144.05(II)). The determination of the optimum dosage and dosage regimen to employ, where the number of treatment days would vary as in the present claims, would have been a matter well within the purview of one of ordinary skill in the art and such determination would have been made in accordance with a variety of factors. These would have included the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered a part of a drug combination. Thus, the

dosage regimen that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent the dosages that would have been determined by the skilled artisan.

Accordingly, for the above reasons, the claims are deemed properly rejected.

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

September 15, 2006